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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,701	10/23/2000	Jang B. Rampal	1956-045	9837

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EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 06/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/694,701

Applicant(s)

RAMPAL ET AL.

Examiner

Joyce Tung

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) 1-28 and 43-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-42 and 55-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

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Response to Amendment

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1637.

1. The amendment filed 3/20/2002 has been entered.
2. The rejection of claims 29-42 under 35 U.S.C. §102(e) anticipated by Head et al. (6,322,968 B1) as set forth in section 7 of the Office action mailed 12/19/2001 is withdrawn because of the amendment and argument.

New Ground Rejections Necessitated by the Amendment

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 56 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention since there is no support in the specification that the probe biopolymer or the target biopolymer is modified. Thus, it constitutes new matter.

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5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 56 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claim 56 is vague and indefinite because of the language "the probe biopolymer or the target biopolymer of step© is modified". It is unclear what is meant by the language "modified".

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 64-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Fareed et al. (4,970,144).

Fareed et al. disclose that a method of detecting a polypeptide contained in a sample comprising the steps of providing a modified substrate (See column 10, lines 19-29) since it is unclear what is meant by the language "modified". A probe polypeptide that can form a complex with the target polypeptide, contacting either the probe or target polypeptide to a surface of the

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substrate to form a probe assay article or a target assay article, contacting the probe assay article or target assay article with the probe peptide or target peptides to form a complex comprising the probe and the target polypeptides and then detecting and determining the presence of the complex (See column 11, lines 34-57). A protein solution is air-dried on the bottoms of wells (See column 11, lines 40-43 and column 13, lines 65-68)) (as recited in the limitations of claim 67). The test antigen can be 10-100 nanogram (See column 11, lines 38-43). This teaching is inherent to the limitations of claim 68. Thus, the teachings of Fareed et al. anticipate the limitations of claims 64-68.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 29-42 and 55-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Head et al. (6,322,968) in view of Groet et al. (4,588,682).

The teachings of Head et al. were set forth in section 7 of the Office action mailed 12/19/2001. Head et al. do not disclose that the probe or target biopolymer is directly adsorbs on the substrate surface as claimed.

Groet et al. disclose that affixing the DNA to the support is carried out by air drying (See column 1, lines 19-22). Groet et al. also further disclose that with organic solvent, immobilizing nucleic acid to a solid support takes very short times, for example, on the order of five minutes or less (See column 1, lines 48-50).

None of the references above discloses the amount of polynucleotide used as claimed in claims 57-60. However, the amount of polynucleotide used as claimed is a common range used in the art at the time of the instant invention.

Thus, it would have been prima facie obvious for an ordinary skill in the art at the time of the instant invention to modify the method of Head et al. by applying air drying for attaching nucleic acid to a solid support in organic solvent (See column 1, lines 25-56) because air drying biopolymer simplifying method procedure. In addition, an ordinary skill in the art at the time of the instant invention would have been motivated to apply the amount of the probe biopolymer or the target biopolymer with a reasonable expectation of success because the modification of the

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reaction condition with a reasonable expectation of success was routine practice in the art at the time of the instant invention since the amount of polynucleotide used as claimed is a common range.

11. Claims 69-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fareed et al. (4,970,144).

The teachings of Fareed et al. are set forth in section 8 above. Fareed et al. do not disclose that the amount of target nucleic acid is applied and the time for air dry as claimed.

However, it would have been prima facie obvious to modify the reaction condition of Fareed et al. by adjusting an amount of the target biopolymer used and the time for air drying the target biopolymer on the surface of substrate as claimed with a reasonable expectation of success because it was routine practice in the art at the time of the instant invention since the amount of polynucleotide used as claimed is in a common range and the time needed for drying the sample is also in a common range.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

June 9, 2002


GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600